DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 20 2002

Ms. Jeanie Ward
586 Somerset Lane #5
Crystal Lake, IL 60014

Re: Docket No. 01P-0244/CP1

Dear Ms. Ward

I am writing in response to your citizen petition dated May 2, 2001, requesting that the Food and Drug Administration (FDA) investigate the use of polyethylene glycol (Miralax) in pediatric patients. The petition describes your daughter's adverse drug events (ADEs) associated with her use of Miralax and requests action on its unindicated use (off-label use).[1]

We understand the concern for your daughter's health and well-being and appreciate the reporting of her ADEs. The FDA empathizes with your situation and assures you that we monitor and investigate all reported incidents of ADEs. The Agency will continue to monitor ADEs associated with the use of Miralax, including its use in pediatric patients.

Your petition indicates that your daughter was 3 years old when she was prescribed Miralax and that she continued to suffer from some of the symptoms 7 months after discontinuing the Miralax treatment. The ADEs reported in your petition include the following:

- Loss of appetite
- A feeling that her throat was closing up
- Shakiness (accompanied by goose bumps) to the point of having seizures (not necessarily after the dose)
- Behavioral changes such as isolation, paranoia, and fear
- Clenching of hands
- Unresponsiveness
- Compulsive behavior
- Night sweats
- Change in sleeping positions

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[1] The petition includes the MEDWATCH report dated October 12, 2000, describing your daughter's ADEs.

You reported that the following additional symptoms developed after your daughter had received 9 to 11 days of treatment with Miralax:

- Panic
- Rapid movements with fingers and tongue
- Sleeplessness during the last two nights of treatment, the last night accompanied by four bowel movements in 90 minutes

Alerting us to the adverse reactions associated with your daughter's use of Miralax is helpful to the Agency in protecting the public health and in ensuring the safe use of drugs in pediatric patients. The gastrointestinal manifestations, nausea, frequent bowel movements, and abdominal discomfort are well-known ADEs associated with the Miralax treatment. But based upon careful examination of the information and symptoms provided in your petition and of the data contained in our adverse event reporting system (MEDWATCH), there is insufficient evidence to require an amendment of the Miralax label at this time. The FDA, however, will continue to closely monitor the adverse experiences reported with this drug and will take the appropriate regulatory action if required under the circumstances.

We hope that your daughter's condition has improved since the submission of your petition to the FDA, but if she continues to experience the symptoms described in your petition, we advise you to seek further medical attention.

Sincerely yours,

for Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research